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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/772,644	01/30/2001	Lawrence S. Barak	033072-007	1059

7590

09/26/2002

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EXAMINER

FALK, ANNE MARIE

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 09/26/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/772,644

Applicant(s)

BARAK ET AL.

Examiner

Anne Falk

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4-6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *detailed action*.

DETAILED ACTION

Claim 1 is pending in the instant application.

Drawings

The draftsman objects to the drawings. See the attached PTO-948.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the specification does not disclose or contemplate a substrate comprising cells that contain a conjugate comprising an **arrestin protein** and a detectable molecule. The specification only contemplates a substrate comprising cells that contain a conjugate of a β -arrestin protein and a detectable molecule. See the specification at page 6, lines 5-7.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer.

A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 48 of U.S. Patent No. 5,891,646. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claim 1 of this application reads on the substrate of Claim 48 of U.S. Patent No. 5,891,646. The species anticipates the genus.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants are referred to the final guidelines on written description published January 5, 2001 in the Federal Register at Volume 66, Number 4, pp. 1099-1111 (also available at www.uspto.gov).

Claim 1 is directed to a substrate having deposited thereon a plurality of cells, said cells expressing at least one GPCR and containing a conjugate, the conjugate comprising an arrestin protein and a detectable molecule. However, the specification does not describe or contemplate a conjugate comprising an arrestin protein other than a β -arrestin protein. The specification only describes a conjugate comprising a β -arrestin protein. See the specification at page 6, lines 5-7. However, the claim is directed to a substrate comprising cells that contain a genus of molecules comprising an arrestin protein. The specification does not contemplate using any arrestin protein other than a β -arrestin protein as a member of the conjugate recited in the claim. This limited information is not deemed sufficient to reasonably convey to one skilled in the art that Applicants were in possession of the claimed substrates at

the time the application was filed. Thus, it is concluded that the written description requirement is not satisfied for the claimed composition.

Enablement

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a substrate having deposited thereon a plurality of cells, said cells expressing at least one GPCR, a GPCR kinase, and containing a conjugate, the conjugate comprising a β -arrestin protein and an optically detectable molecule, does not reasonably provide enablement for a substrate as claimed, wherein the conjugate comprises an arrestin protein and a detectable molecule. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claim is directed to a substrate having deposited thereon a plurality of cells, said cells expressing at least one GPCR and containing a conjugate, the conjugate comprising an arrestin protein and a detectable molecule.

The specification fails to provide an enabling disclosure for the claimed composition because the specification teaches that the only use of the claimed composition is for assaying receptor activity, but the specification does not teach how to use an arrestin other than a β -arrestin for assaying receptor activity. The specification does not provide any guidance with regard to receptors that bind an arrestin protein other than a β -arrestin protein. The teachings of the specification are limited to the role of β -arrestin in mediating receptor activity. The specification does not offer specific guidance with regard to the role of an arrestin other than a β -arrestin in mediating receptor activity. Thus, one of skill in the art would not know which arrestin to use in combination with which receptor to set up an appropriate assay system and undue experimentation would have been required to determine the role of other arrestins in mediating receptor activity.

The specification fails to provide an enabling disclosure for the claimed composition because in the absence of a **phosphorylated** receptor or the necessary receptor kinase that would phosphorylate the receptor. The specification teaches that β -arrestin binds to the phosphorylated μ opioid receptor. However, the claimed composition does not include a phosphorylated receptor or require that the necessary cognate receptor kinase (GRK) be present in the cells. The specification teaches at pages 1-7 that a GPCR kinase is responsible for phosphorylation of the μ opioid receptor. At page 28, lines 3-27, the specification clearly discloses that β -arrestin binds to the **phosphorylated** GPCR. Thus, one of skill in the art would immediately recognize that the cell being used in the assay must also comprise the necessary receptor kinase to permit β -arrestin to bind to the receptor. Furthermore, the specification clearly teaches that the cell must comprise the **phosphorylated** receptor (see specification at page 28, lines 25-27). The claims encompass substrates comprising cells that does not comprise the cognate receptor kinase, but the specification is not enabling for this scope of the claim. The specification does not teach how to use a cell that does not comprise the cognate receptor kinase, and one of skill in the art would not expect that the assay could be performed using such a cell.

The specification fails to provide an enabling disclosure for a substrate comprising cells containing a conjugate of an arrestin protein and a “detectable molecule” because the specification does not teach how to use a variety of “detectable molecules” but rather only teaches how to use an optically detectable molecule. **All molecules are detectable molecules.** However, the specification clearly teaches that the conjugate must comprise a molecule that can be detected visually, as the disclosed assay method relies on being able to pinpoint the **cellular localization** of the complex (i.e., β -arrestin conjugated to the optically detectable molecule). At page 3, lines 15-16 and lines 23-25 of the specification, the disclosure teaches the use of an “optically detectable molecule” such as green fluorescent protein for detecting translocation of β -arrestin from the cytoplasm to the cell membrane. However, the claim covers the use of any detectable molecule which means that it covers the use of

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virtually any molecule, or at least any protein molecule because all proteins can be detected using antibodies, in a variety of ways. For example, an antibody can be used to merely detect the **presence** of a protein in a sample. Such detection need not detect the **cellular localization** of the protein being detected. Thus, β -arrestin itself would constitute a detectable molecule, as anti- β -arrestin antibodies could be raised for its detection. Thus, **all molecules are detectable molecules**. However, in this particular instance, to enable the assay method disclosed in the specification, the **detectable molecule** must be able to pinpoint the cellular localization of the complex (β -arrestin conjugated to the optically detectable molecule) and therefore **the detectable molecule must be visually detectable**. Given the teachings of the specification and the prior art, one of skill in the art would not know how to detect the cellular localization of a particular molecule (in this case β -arrestin) other than by visual means. Limitation to the use of an optically detectable molecule is therefore appropriate.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in its recitation of "a detectable molecule" because all molecules are detectable molecules and therefore it is unclear how said "detectable molecule" would be distinct from any other molecule. The metes and bounds of the claim are not clearly set forth.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (703) 306-9155. The examiner can normally be reached Monday through Thursday and alternate Fridays from 10:00 AM to 7:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Anne-Marie Falk, Ph.D.

Anne-Marie Falk
ANNE-MARIE BAKER
PATENT EXAMINER